JAN 3 0 2004

K033590

510K SUMMARY

Submitted By: ERBE USA, Inc.
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Contact Person: John Tartal

Date Prepared: 11/11/03

Common Name: Water Jet Dissector

Trade/Proprietary Name: Helix Hydro-Jet™

Classification Name: Jet Lavage (21CFR880.5475)

Product Code: FQH

Legally Marketed Device: Helix Hydro-Jet

Note: This 510(k) is being submitted to expand the intended use for the Helix Hydro-Jet.

Device Description:

The Helix Hydro-Jet is a hydraulic pressure delivery system that uses physiological saline to cut and dissect soft tissue. A very detail description of the system can be found in the initial 510(k), Number K012464, Device Description 1-1.

Note: A summary of design control activities, risk analysis, verifications/validations, and biocompatibility can also be found respectively in Sections 4-1, 5-1, 6-1, 9-1, and 8-1 of the initial 510(k). Also, certifications and the declaration of conformity are in the first 510(k) Appendices A and B respectively.

Intended Use:

The Helix Hydro-Jet is intended for the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery.

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

The modified device is the same as the predicate except for slight modifications to the unit's suction connector/tubing as well as the suction container and bag since the last 510(k) submission (K022613). The suction connector/tubing was change so that only

the tubing for the suction container/bag could be connected. Also, the container and bag were made larger from a 1,000 ml to 2,000 ml capacity (dimensional/size change). Changes to the label and labeling are apart of this submission (See IV-4 to IV-48). The suction connector/tubing, container, and bag were verified/validated in design control. Risk analysis also has been performed with regards to changing the part, component, and accessory.

The significant change involves the expansion of the indications as follows.
1. Addition of using the device to cut and dissect soft tissue in neurosurgery.
The change to the intended use is supported by scientific documentation provided in this Section as a part of Clinical Evaluations (See III-9).

Conclusion:

All available/known studies involving the Helix Hydro-Jet and like water jet equipment in conjunction with the expanded intended use has been provided in this submission (Note: An exhaustive literature search was performed.). The water jet is a non-thermal, selective instrument which preserves structures with higher fibrin content such as vessels, nerves, and ducts (including arachnoid membranes). With its accuracy and non-thermal modality damage to surrounding tissues is minimized. As a result, in neurosurgery less tissue necrosis and edema can reduce post-operative neurological symptoms. Furthermore, sparing of vessels can result in less blood loss. The clinical documentation provided demonstrates that the Helix Hydro-Jet may be used safely and effectively to cut/dissect soft tissue in neurosurgery. Summary of the studies are as follows.

Animal Studies
In experimental trials with porcine brain cadaveric tissue, scientists investigated nozzle sizes, pressures, penetration depths (based upon cutting distance and speed), and effects on various brain tissues. As a result, the attributes of the hand piece were better defined. The optimal size of the nozzle/helical water jet stream was found to be 120 *u*m (Note: Current attribute of Helix Hydro-Jet Applicators) and with better technique as well as use of suction, clogging of an applicator and foaming at the surgical site obscuring visibility was virtually eliminated. Also with this jet stream size, linearity in regard to pressure and penetration depths was established. The studies showed brain parenchyma was well dissected using 3 to 12 bars (43.5 to 174 psi). Cuts were extremely sharp and precise. In surrounding tissue no disruption or vacuolization was seen. Depth of penetration was determined to be depended upon the density/consistency of the tissue dissected and ranged from 3 to 19 mm. Vessels as small as 0.3 mm were found to be spared between 3 and 7 bars (43.5 to 101.5 psi).

Human Studies
The Helix Hydro-Jet was used on patients with various brain tumors (e.g., gliomas, metastastic lesions, meningiomas, etc.) and epilepsy (Note: Published literature largest patient population was 75.). In general; the applicators were easy to handle,

dissections (separation and removal) were accurate/successful on malleable soft tissues (brain parenchyma or tumors), vessels in some cases were spared up to 25 bars (362.5 psi), and there was no thermal damage to surrounding tissue. In particular, the device was found to be efficacious in soft tissue dissection near vital structures where precision and less tissue trauma is paramount. However, due to the advantage of being selective based upon solidity/density, the device becomes harder to use on firmer masses or structures (e.g., to dissect tumor capsules, separate/remove dense tumors, cut fibrous appendages like trabecular structures, etc.). As a result, this issue was addressed as a precaution in the User Manual. Nonetheless, the Helix Hydro-Jet showed to be an effective tool and should be included in the neurosurgical armamentarium (Note: The higher risks of infection or tumor spreading due to the almost permanent water rinsing has been raised as a possible potential disadvantages of the device. However, current results do not support the complications of a higher risk of infection, an increase of tumor recurrence, or tumor spreading.).

Investigations Comparing Helix versus CUSA

Tissue trauma after neurosurgical procedures on 55 rabbits was investigated respectively with the Helix Hydro-Jet and Cavitational Ultrasonic Surgical Aspirator (CUSA). Neurosurgery was performed on the animals, and then they were sacrificed at various time points for tissue examination. At all time points, there was less edema formation as well as less intense microglial and astroglial reaction in neurological tissues of rabbits operated on with the Helix Hydro-Jet in comparison to the CUSA. As a result, the water jet has to be considered as less traumatic than the ultrasonic aspirator. Furthermore the Helix Hydro-Jet was compared to CUSA in neurosurgery on 102 humans. The Helix Hydro-Jet was used in combination with conventional methods in tissue dissection and aspiration. In comparison with CUSA, there were two specific advantages with the Helix Hydro-Jet (1) The waterjet enabled brain parenchyma tissue dissection and vessel coagulation without thermal damage to the remaining tissue as well as (2) dissection of tissue without damage to the arachnoid membranes. CUSA could not achieve these accolades concluding that in certain conditions the waterjet is more suitable.

In conclusion, the use of the Helix Hydro-Jet on soft tissue in neurosurgery was found to be safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2004

Mr. John Tartal
Manager, Quality Assurance/Regulatory Affairs
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, Georgia 30067

Re: K033590
Trade/Device Name: ERBE Helix Hydro-Jet™
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: II
Product Code: FQH
Dated: November 11, 2003
Received: November 10, 2003

Dear Mr. Tartal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

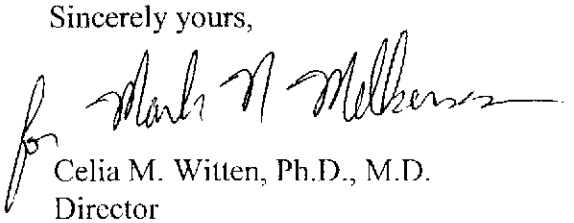
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (If Known): K033590

Device Name: ERBE Helix Hydro-Jet™

Indications for Use:

The Helix Hydro-Jet is intended for the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery.

Prescription Use ___X___ AND/OR Over-the-Counter Use ________
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

fr Mark N Melkerson

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